

## EXHIBIT 3

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE NORTHERN DISTRICT OF OHIO

3 EASTERN DIVISION

4 - - -

5 IN RE: NATIONAL : HON. DAN A.  
6 PRESCRIPTION OPIATE : POLSTER  
7 LITIGATION :  
8 APPLIES TO ALL CASES : NO.  
9 : 1:17-MD-2804  
10 :  
11

12 - HIGHLY CONFIDENTIAL -

13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

14 VOLUME I

15 - - -

16 April 17, 2019

17 - - -

18 Videotaped deposition of  
19 THOMAS PREVOZNIK, taken pursuant to  
20 notice, was held at the law offices of  
21 Williams & Connolly, 725 12th Street,  
22 Washington, D.C., beginning at 9:11 a.m.,  
23 on the above date, before Michelle L.  
24 Gray, a Registered Professional Reporter,  
Certified Shorthand Reporter, Certified  
Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES  
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deps@golkow.com

1 system in use by wholesale drug  
2 distributors for controlled substances,  
3 do you see that reference that you just  
4 read?

5 A. Yes.

6 Q. Is it fair to say then,  
7 there was in fact at this point in time,  
8 in 1998, a DEA-approved suspicious order  
9 monitoring system for controlled  
10 substances?

11 A. I would say no, because  
12 there was never a -- DEA never had an  
13 approved system. The system that the  
14 statute requires and the regulations  
15 require is the registrant is to design  
16 and operate that system.

17 They come to us and they  
18 say, here's our system, and we may have  
19 discussions with them about it. So you  
20 can have a great system in paper, but  
21 when you implement it, are you actually  
22 implementing what you say.

23 So that's part of our job,  
24 when we go out there for schedule

1 investigation, is to look at that program  
2 and are they doing what they're saying,  
3 is it actually detecting suspicious  
4 orders.

5 Q. So, Mr. Prevoznik, try to  
6 listen to my question and answer it. I  
7 realize that you would like to speechify  
8 a little bit and get out your talking  
9 points, but please restrain --

10 MR. FINKELSTEIN: Try not to  
11 argue with the witness.

12 BY MS. MAINIGI:

13 Q. -- from doing that.

14 MR. FINKELSTEIN: You can  
15 ask your questions. And you're  
16 not here to abuse him.

17 BY MS. MAINIGI:

18 Q. So, Mr. Prevoznik, let's  
19 back up. The DEA helped to write this  
20 report, right?

21 A. Correct.

22 Q. And someone from the office  
23 of diversion control at the DEA was in  
24 fact the chair of the group that wrote

1           Q.     And did you read far enough  
2     in the report to see that there was, in  
3     fact, an algorithm that was contained as  
4     an exhibit to the report?

5           A.     Do you have a page number?

6           Q.     Sure:   Bates Number 2247.

7                     Did you review this page  
8     previously?

9           A.     Yes.

10          Q.     Okay.   And -- and this page  
11     essentially contains a calculation or  
12     algorithm for both List I chemicals and  
13     Schedule II controlled substances,  
14     correct?

15          A.     Correct.

16          Q.     Now, DEA did not require  
17     distributors to use a particular  
18     algorithm or metric to identify excessive  
19     purchases of controlled substances,  
20     correct?

21          A.     Could you please repeat  
22     that?

23          Q.     DEA did not require that a  
24     distributor use a particular calculation

1 or algorithm to identify excessive  
2 purchases of controlled substances,  
3 correct?

4 A. Correct.

5 Q. But, the DEA was aware that  
6 certain registrants were using a  
7 calculation or metric or algorithm to  
8 identify an excessive purchase, correct?

9 MR. FINKELSTEIN: Objection.

10 Vague as to time.

11 THE WITNESS: I -- I just  
12 want to make sure I'm clear on  
13 this. We're talking about  
14 excessive purchases or are we  
15 talking about suspicious orders?

16 BY MS. MAINIGI:

17 Q. Well, right now I'm talking  
18 about excessive purchase reports in this  
19 time period.

20 Was the DEA aware that in  
21 approximately the 1998 time period, that  
22 distributors were using a particular  
23 algorithm or calculation to identify  
24 excessive purchases of controlled

1                   Was the DEA aware that  
2                   certain employees had, in fact, blessed  
3                   the excessive purchase reporting systems?

4                   MR. FARRELL:  Objection.

5                   Foundation.

6                   THE WITNESS:  I don't know  
7                   which employees you're speaking  
8                   of.

9                   BY MS. MAINIGI:

10                  Q.       Just employees.  Is -- is it  
11                  fair to say that the DEA did, in the late  
12                  '90s and early aughts, from time to time  
13                  review the reporting systems of  
14                  distributors and essentially give them a  
15                  yay or nay as to whether they thought  
16                  that the reporting system was suspicious?

17                  MR. FARRELL:  Objection.

18                  Foundation.

19                  MR. FINKELSTEIN:  Objection.

20                  Vague.

21                  THE WITNESS:  You lost me on  
22                  the last part.

23                  BY MS. MAINIGI:

24                  Q.       Okay.  Let me start over.

1                   We -- we established before  
2                   that the DEA today does not review  
3                   reporting systems, right?

4                   MR. FINKELSTEIN: Objection.

5                   Mischaracterizes the witness's  
6                   testimony.

7                   THE WITNESS: I mean, we --  
8                   we reviewed McKesson's, the new  
9                   one.

10                  BY MS. MAINIGI:

11                  Q.     And you left it --

12                  A.     -- we reviewed it, we -- we  
13                  did not -- we --

14                  MR. FINKELSTEIN: Let the  
15                  witness answer the question.

16                  THE WITNESS: I don't know  
17                  what you mean by the term  
18                  "blessing it."

19                  BY MS. MAINIGI:

20                  Q.     Okay.

21                  A.     Because as I had said  
22                  previously, that you -- you can write the  
23                  best system in the world, but if you  
24                  don't implement it and you don't stick to

1 it, it doesn't mean anything.

2 So that's part of our  
3 review, when we go out and do schedule  
4 investigations, is to review, are they  
5 factually, in fact -- did -- is -- are  
6 they operating a system that can detect a  
7 suspicious order.

8 BY MS. MAINIGI:

9 Q. And that's something that  
10 the DEA reviews periodically as part of  
11 its auditing process, correct?

12 A. Correct.

13 Q. So as part of the audit  
14 process, operating systems that are  
15 designed to review suspicious orders are  
16 reviewed by the DEA?

17 A. Well, it's not just the  
18 schedule. I mean it could be a  
19 pre-registration, somebody is coming on  
20 and they have -- we have to go through  
21 the whole public interest of, you know,  
22 what do you have in place to operate and  
23 detect a system. So it's not just a  
24 schedule investigation. There are

1 schedule investigations that we follow  
2 up, and we do that as well. So it comes  
3 in -- it comes in various times that  
4 we're going to review somebody's  
5 operating system, whether we're on  
6 schedule investigation, or whether we're  
7 doing an investigation on a pharmacy or  
8 something like that, where we're going to  
9 look at how many SORs were submitted or  
10 not submitted, or we're going to look at  
11 the ARCOS data, how much did they buy.

12 We're going to look at  
13 various things to make the determination  
14 on what is going on.

15 Q. And if either in the  
16 pre-registration process or in the audit  
17 process the DEA determines that a  
18 registrant's system is not adequately  
19 detecting suspicious orders, is that  
20 something that is conveyed to the  
21 registrant?

22 A. Yeah, we -- we would tell  
23 them, you need to add something.

24 Q. It's clear in the Rannazzisi

1 the characterization.

2 THE WITNESS: Nationwide,  
3 correct.

4 BY MS. MAINIGI:

5 Q. Instead, one-off guidance  
6 was perhaps provided in the context of  
7 individual distributor meetings, correct?

8 A. Yes. Along with the MOAs  
9 and the settlements that were done.

10 Q. And is there documentation  
11 of what was said at the individual  
12 distributor meetings?

13 A. It would be the PowerPoints  
14 and the report -- after report.

15 Q. And this is an internal DEA  
16 report?

17 A. Yes.

18 Q. And have you reviewed those  
19 internal DEA reports for the purpose of  
20 preparing for your testimony today?

21 A. Some of them.

22 Q. Now, does the DEA agree that  
23 there's more than one way to design and  
24 operate a system that can identify and

1 report suspicious orders?

2 A. Yes.

3 Q. And there's no single  
4 feature that makes a suspicious order  
5 monitoring system compliant, correct?

6 A. Correct.

7 Q. And the DEA leaves it up to  
8 the registrant to design a system that  
9 works with its own business model and  
10 customer base, correct?

11 A. Correct.

12 Q. Does it matter to the DEA  
13 whether a registrant reviews orders  
14 manually or uses an automated system?

15 A. No, it doesn't matter.

16 Q. Other than requiring that  
17 the report, suspicious order report  
18 clearly indicate that the order is  
19 suspicious, does DEA require suspicious  
20 order reports to follow a particular  
21 format?

22 A. That's correct.

23 Q. Let me ask the question  
24 again. The DEA does not require

1 suspicious order reports to follow a  
2 particular format, correct?

3 A. Well, I mean, they have to  
4 follow what the regs say about unusual  
5 size, unusual patterns, or frequency. I  
6 mean, that's in there. We also ask that  
7 the red flags and, you know, looking at  
8 newspapers articles to see, you know,  
9 what the overdoses are. You know, are  
10 they looking at more than just the data,  
11 because the data is only as good as --  
12 you know, you can set the threshold too  
13 high, you can set it too -- it's never  
14 going to pick up something, or you're not  
15 going to see patterns, because it's a new  
16 customer that gets onboarded, and they're  
17 already high, and you don't question it  
18 or you don't look at it, you don't see  
19 the population size, you don't see what's  
20 their percentage of control versus not  
21 control. I mean, there's a lot of  
22 different factors that go in it. So  
23 however they design it, they need to get  
24 the big picture so that they truly know

1       what is their customer doing.

2               Q.       Is there --

3                       MR. FINKELSTEIN:   Hang on.

4               Five minutes ago, I asked for a

5               break.   We've been on the record

6               for more than an hour and a half.

7               Can you tell us when you are going

8               to be done?

9                       MS. MAINIGI:   Just a couple

10              more minutes.

11      BY MS. MAINIGI:

12              Q.       Is the review -- is it fair

13      to say then that the identification of

14      suspicious orders can be a subjective

15      process?

16                       MR. FINKELSTEIN:   Objection.

17              Vague.

18                       THE WITNESS:   What do you

19              mean by "subjective"?

20      BY MS. MAINIGI:

21              Q.       Well, do you understand the

22      meaning of the word "subjective"?

23              A.       I'm asking you in terms of

24      this, what do you mean by subjective?

1           that this is outside the scope.

2           I'll let the witness answer for  
3           now if you have understanding.

4                   THE WITNESS:   Yes.

5   BY MR. STEPHENS:

6           Q.     Is it also true under -- you  
7           testified earlier today about the C.F.R.  
8           regulations, correct?

9           A.     Correct.

10          Q.     And under Title 21 -- or I'm  
11         sorry, under 21 C.F.R. 1301.71(b), it's  
12         true that the regulation regarding  
13         suspicious order monitoring does not  
14         require strict compliance, it requires  
15         substantial compliance?

16                   MR. FINKELSTEIN:   Did you  
17         mean 74?

18                   MR. STEPHENS:   It might be  
19         74.

20                   MR. FARRELL:   1301.74(b)?

21                   MR. STEPHENS:   Yes.   No,  
22         actually -- here.   Let me just  
23         mark it.

24                   (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-13.)

3 BY MR. STEPHENS:

4 Q. I'll show the witness what's  
5 been marked as Exhibit 13.

6 A. So, (b)?

7 Q. (B), right.

8 A. Okay.

9 Q. So (b) states substantial  
10 compliance with the standards set forth,  
11 right?

12 A. Yes.

13 Q. Okay. And that could be  
14 deemed sufficient, correct?

15 A. Yes. That's what it says.

16 Q. It does not say strict  
17 compliance, correct?

18 A. Correct.

19 Q. Like manufacturers and  
20 distributors, DEA also considers doctors  
21 who prescribe opioids to their patients  
22 to be registrants?

23 A. Correct.

24 Q. Okay. The prescribing

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE NORTHERN DISTRICT OF OHIO

3 EASTERN DIVISION

4 - - -

5 IN RE: NATIONAL : HON. DAN A.  
6 PRESCRIPTION OPIATE : POLSTER  
7 LITIGATION :  
8 APPLIES TO ALL CASES : NO.  
9 : 1:17-MD-2804  
10 :  
11

12 - HIGHLY CONFIDENTIAL -

13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

14 VOLUME II

15 - - -

16 April 18, 2019

17 - - -

18 Continued videotaped  
19 deposition of THOMAS PREVOZNIK, taken  
20 pursuant to notice, was held at the law  
21 offices of Williams & Connolly, 725 12th  
22 Street, Washington, D.C., beginning at  
23 8:16 a.m., on the above date, before  
24 Michelle L. Gray, a Registered  
Professional Reporter, Certified  
Shorthand Reporter, Certified Realtime  
Reporter, and Notary Public.

- - -

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1           speculating on that, but, yes.

2       BY MR. STEPHENS:

3           Q.     Okay. I'd like to continue  
4       by asking you some additional questions  
5       about interpretation enforcement of  
6       Title 21 U.S.C. 23, the regulations and  
7       how those relate to the design of a  
8       reasonable SOMs system. Okay?

9           A.     Yes.

10          Q.     Okay. So yesterday you --  
11       you testified about different  
12       distributors having different business  
13       models, right?

14          A.     Correct.

15                 MR. FINKELSTEIN: Objection.

16       Scope. Characterization.

17       BY MR. STEPHENS:

18          Q.     Is it fair to say that a  
19       SOMs systems is not a one-size-all  
20       proposition, one-size-fits-all  
21       proposition?

22          A.     Correct.

23          Q.     And DEA understands that not  
24       all registrants distribute opioids to the

1 same customers, right?

2 A. Correct.

3 Q. DEA understands that  
4 registrants have different business  
5 models?

6 A. Correct.

7 Q. And DEA expects that each  
8 registrant will review its own business  
9 model and design a SOM system that fits  
10 its specific method of distribution?

11 MR. FINKELSTEIN: Objection.

12 Vague.

13 THE WITNESS: That's correct  
14 as -- as per the regulations.

15 BY MR. STEPHENS:

16 Q. Okay. Some registrants  
17 distribute to hospitals?

18 A. Correct.

19 Q. Some don't?

20 A. Correct.

21 Q. Some registrants distribute  
22 to hospice centers?

23 A. Correct.

24 Q. Some don't?